Automated Med. Labs., Inc., 471 U.S. 707, 712 (1985) (internal quotation omitted). Federal preemption may be "either expressed or implied, and 'is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Gade v. National Solid Wastes Mgmt. Ass'n,* 505 U.S. 88, 98 (1992) (quotation omitted). Absent express preemptive language from Congress, the Supreme Court has recognized that state law is implicitly preempted if it conflicts with federal law. *See id.*

State law is preempted "to the extent that it actually conflicts with federal law." *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta,* 458 U.S. 141, 153 (1982). A conflict arises where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Massachusetts Med. Soc'y v. Dukakis*, 815 F.2d 790, 791 (1st Cir. 1987). Preemption is also appropriate where complying with both the federal and state regulatory schemes is impossible. *Fidelity*, 458 U.S. at 153. Moreover, where state law claims rest on allegations that misrepresentations were made to a federal agency, such "fraud on the agency" claims are preempted when (1) an "extensive mechanism" for federal enforcement exists, and (2) permitting such claims would "upset the delicate balance" of federal statutory objectives. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347-53 (2001).

In *Buckman*, plaintiffs claiming to have suffered injuries from an orthopedic product sued the manufacturer's regulatory consultant for allegedly making fraudulent representations to the FDA in the course of the FDA approval process. *Id.* at 344. A unanimous Court ruled that the state law claims were impliedly preempted, under the doctrine of conflict preemption, by the Medical Device Amendments to the Food, Drug and Cosmetics Act (the "MDA"). *Id.* at 347. The Court first observed that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,'" and thus concluded that the usual "presumption against finding federal preemption of a state-law cause of action" did ***not*** apply. *Id.* On the contrary, the

Court reasoned that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* State law "fraud on the agency" claims, in contrast, "inevitably conflict with the FDA's responsibility to police fraud" and, "[as] a practical matter, complying with the FDA's detailed regulatory regime in the shadow of the 50 States' tort regimes will dramatically increase the burdens facing potential applicants -- burdens not contemplated by Congress in enacting the FDCA and the MDA." *Id.* at 350. "Given this analytical framework," the Court concluded, the plaintiffs' state law claims conflicted with and were impliedly preempted by the MDA. "The conflict stems," the Court ruled, "from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud" in order to achieve a "delicate balance of statutory objectives." *Id.* at 348.

Buckman compels a finding that the Montana and Nevada Best Price claims are preempted by the Rebate Statute. First, like the *Buckman* "fraud on the FDA" theory, the Best Price claims here are based on alleged misrepresentations submitted to a federal agency (HHS), not to the States. As the Court pointed out in *Buckman*, policing fraud against federal agencies is not a traditional function of state law. *Id.* at 347. In fact, the federal interest here is far more powerful than in *Buckman*, as the "policing" function that the States seek to assume here relates to a contract between each manufacturer and the federal government -- not the States. *See, e.g., Boyle v. United Technologies Corp.*, 487 U.S. 500, 503 (1988) (recognizing that contracts to which the federal government is a party implicate "uniquely federal interests"). Second, like the FDA in *Buckman*, HHS has an extensive array of enforcement mechanisms at its disposal under the rebate program to "punish and deter fraud against it." 531 U.S. at 348-50. Both the Rebate Statute and the Rebate Agreement authorize the Secretary to survey drug manufacturers to verify prices and the calculation of "Best Prices." *See* 42 U.S.C. § 1320a-7c; Rebate Agreement

§§ III(b)-(c). If a manufacturer refuses to comply with an audit or fails to provide timely or accurate information regarding its best price, only the Secretary may impose fines. *See* 42 U.S.C. § 1396r-8b(3)(B & C). The Secretary also has the sole power to impose civil monetary penalties, exclude entities from participation in federal health programs, and direct state Medicaid agencies to debar them. *See* 42 U.S.C. § 1320a-7a. The only role for the States in the administration of the Medicaid rebate program is to supply particular utilization data by drug. *See* 42 U.S.C. § 1396r-8(b)(2)(A).[5]

Third, as in *Buckman*, Montana and Nevada's Best Price claims raise the specter of a patchwork of liability and reporting requirements across the country that would present insuperable compliance obstacles and upset the "delicate balance of statutory objectives." *Buckman*, 531 U.S. at 347-50. As in *Buckman*, if federally-defined terms such as best price are defined under individual state laws (as the States desire), "[as] a practical matter, complying with [HHS'] detailed regulatory regime in the shadow of 50 States' [laws] will dramatically increase the burdens facing" the manufacturers that participate in the Medicaid rebate program. *Id.* at 348, 350. For example, if "best price" is defined one way under the Montana Medicaid fraud statute, and another way under the Nevada Medicaid fraud statute, each participating manufacturer will be required to file state-specific best price quarterly reports with HHS, rather than the single, unified report to HHS that is currently required under the Rebate Agreement. Obviously, filing a Montana best price report, a Nevada report, and other state-specific reports with HHS would "dramatically increase" the burdens on participating manufacturers. CMS, in

[5] The federal investigations involving compliance with the Medicaid rebate statute referenced in the Nevada and Montana complaints also reinforce the primacy of the federal government in the rebate program. Those investigations were conducted by HHS and the Department of Justice. *See* Nev. Cplt. ¶¶ 398-400, Mont. Cplt. ¶¶ 628-30 (referencing AstraZeneca settlement); Nev. Cplt. ¶¶ 401-403, Mont. Cplt. ¶¶ 631-34 (referencing Warner-Lambert settlement involving Lipitor); Mont. Cplt. ¶¶ 617-19 (referencing GSK settlement involving Flonase and Paxil) and ¶¶ 621-27 (referencing Bayer settlement involving Cipro and Adalat CC).

turn, would also be forced to process and evaluate these numerous state-specific reports, and to issue different "Unit Rebate Amounts" for each covered drug and dosage by State. *See* 42 U.S.C. § 1396r-8(b)(2)(A). This would turn the Medicaid rebate program on its head, as CMS, not the States, is required to calculate the rebate amounts owed to each State using the uniform best price calculations. *Id.* This multi-report regime would impose an enormous burden on CMS and jeopardize CMS' very ability to administer the Medicaid rebate program. Such a Balkanized, burdensome regulatory regime is precisely what the Court prohibited in *Buckman*. *See* 531 U.S. at 349-50.

Finally, as this Court has already found in connection with the ruling on removal, if the States "were to prevail on the best price claims, it could result in *substantial changes* in the Medicaid reimbursements paid out by the federal government." *State of Montana,* 266 F. Supp.2d at 259 (emphasis added). As other courts have ruled in connection with other provisions of the Medicaid Rebate Statute, the imposition of such "substantial changes" in Medicaid reimbursement cannot be predicated on state law. Specifically, several courts have already concluded that Medicaid co-payment regulations that reduced reimbursement levels to pharmacists for certain covered drugs were preempted by a provision in the Rebate Statute that imposed a "moratorium" on "reducing dispensing fees for such drugs." 42 U.S.C. § 1396r-8(f)(1)(B). After the district court held that such state regulation was preempted because it "conflict[ed] with federal law in an area where Congress has clearly intended to create uniformity," *Pharmaceutical Soc'y of N.Y., Inc. v. New York State Dep't of Social Servs.,* 1994 WL 33369, *6 (N.D.N.Y. Jan. 18, 1994), *aff'd*, 50 F.3d 1168 (2d Cir. 1995), the Second Circuit affirmed, adding that the mere effect of the state regulation was sufficient for conflict preemption, regardless of the State's intent. *See* 50 F.3d at 1172 ("to the extent that the State's co-payment system results in the reduction of payments to pharmacists . . . it is preempted.").

See also Nebraska Pharmacists' Ass'n v. Nebraska Dep't of Social Servs., 863 F. Supp. 1037, 1043 (D. Neb. 1994) (state law preempted for impermissible "tinkering with the formulas used to calculate the reimbursement limits"); *Indiana Pharmacists Ass'n v. Indiana Family & Soc. Servs. Admin.*, 881 F. Supp. 395, 398 (S.D. Ind. 1994) (same result). Similarly, in this case, the States' Best Price claims seek to "tinker" with nationally-uniform "best price" reimbursement calculations that "could result in substantial changes" in Medicaid reimbursement, as the Court has already held.

B. The Best Price Claims Also Fail Under Montana and Nevada Law.

Even if the Best Price Claims were not preempted, they fail under the Montana and Nevada Medicaid Fraud statutes (Mont. Count III; Nev. Count V) and Montana's False Claims Act (Mont. Count IV).[6]

1. Plaintiffs Fail to State Claims Under the Montana and Nevada Medicaid Fraud Statutes.

At the outset, it is important to recognize that these state statutes are intended to combat fraud by "providers," such as physicians and pharmacies who submit claims for payment to and receive reimbursement from the Montana and Nevada state Medicaid programs. *See* Mont. Code Ann §§ 53-6-160(2)-(3); Nev. Rev. Stat. §§ 522.580(b)(1)(a)-(b) (setting penalties against a "*provider* who receives payment to which he is not entitled."). For this reason, Montana law authorizes claims for Medicaid fraud only against persons or entities who have "submit[ted] to a Medicaid agency an application, claim, report, document, or other information." Mont. Code Ann. § 53-6-160(1). A "Medicaid agency," in turn, is defined by law as "any agency or entity of state, county, or local government that administers any part of the medicaid program." *Id.* § 53-

[6] The Best Price claims that purport to allege violations of Montana and Nevada's "deceptive trade practice" statutes should be dismissed as preempted (*supra* pages 6-11) and for failure to satisfy Rule 9(b) (*infra* pages 18-20).

6-155(9). Similarly, the Nevada statute also requires that claims for Medicaid fraud be based on the submission of a claim, statement, or representation "with respect to the plan," which is the state Medicaid plan. Nev. Rev. Stat. §§ 422.480, 422,540(1). The Montana and Nevada statutes also premise liability for Medicaid fraud on the submission of information used to determine the amount of a "payment" under the Medicaid program. *See* Mont. Code Ann. § 53-6-160(1) (requiring submission of information "used to determine . . . the amount of payment under the medicaid program"); Nev. Rev. Stat. § 422.470 (defining "claim," for Medicaid fraud purposes, as a communication used "to determine a rate of payment pursuant to the plan").

The Montana and Nevada Medicaid fraud claims cannot satisfy these requirements. First, the defendants do not submit claims, reports, or other information to any state agency in Montana or Nevada under the Medicaid rebate program. On the contrary, participating manufacturers submit best price reports only to CMS. Second, neither Montana nor Nevada uses the best price data in determining the amount it pays for drugs under Medicaid. Montana reimburses most providers for most prescription drugs at AWP-15% (Mont. Cplt. ¶ 162), and Nevada reimburses for most drugs at AWP-10% plus a dispensing fee (Nev. Cplt. ¶ 126). Thus, the best price reports to HHS cannot be the basis for claims under the state Medicaid fraud statutes. *See* Mont. Code Ann. § 53-6-160; Nev. Rev. Stat. § 422.470.

2. Montana Fails to State a Claim Under Its "False Claims" Act.

Montana's assertion of state law False Claims act violations fails for similar reasons. Under the Montana False Claims Act, a claim is actionable only if the claim is submitted to a "state agency or its contractors." Mont. Code Ann. § 17-8-231(1). In the Best Price claims, there was no claim made to "state agency or its contractors." Indeed, there was no "claim" at all, which is defined as a communication "used to claim specific services or items as payable or reimbursable" or "to determine entitlement to or the rate of payment under the medicaid

program." Mont. Code Ann. § 53-6-155(4). The best price reports to CMS are not "claims" under the Montana False Claims act because the reports do not "claim specific services or items," nor are they used by the State to "determine entitlement to or the rate of payment" under the State's Medicaid program. *Id.*

II. THE AWP CLAIMS FAIL UNDER MONTANA AND NEVADA LAW.

Montana and Nevada assert AWP claims under their "deceptive trade practice" statutes on behalf of Medicare beneficiaries and private health plans (in a *parens patriae* capacity). *See* Mont. Count I; Nev. Counts I-II. The States also assert on their own behalf that the alleged AWP "misreporting" violates the "deceptive trade practice" statutes (Mont. Count II; Nev. Count III). Nevada further claims that the AWP conduct violates Nevada's civil RICO statute (Nev. Count IV), and Montana claims that it violates the State's False Claims act (Mont. Count IV).

A. Montana and Nevada Cannot Recover Under Any Fraud or Deception-Based Theory for Their Voluntary Decision to Base Drug Reimbursement Under Medicaid on AWP.

The AWP claims asserted on the States' own behalf are prosecuted under the Nevada and Montana "deceptive practices" statutes , the Nevada civil RICO provision, and the Montana False Claims act. All of these claims are based on the core allegation that defendants defrauded and misled the States by publishing inflated AWPs. Mont. Cplt. ¶ 173; Nev. Cplt. ¶ 136 ("Defendants simply fabricated and overstated their AWPs in furtherance of a scheme to generate profit spreads to providers, PBMs and others and to increase defendants' profits at the expense of Patients and programs such as the Montana [and Nevada] Medicaid Program."). These claims cannot survive if the States were aware that the published AWPs bore "little relationship to the drugs' pricing in the marketplace." *Id. See, e.g., Kennedy v. Josephthal & Co.*, 814 F.2d 798, 802 (1st Cir. 1987) (fraud plaintiff not misled when previously "on notice that something may have been amiss"); *J. Geils Band Employee Benefit Plan v. Smith Barney*

Shearson, Inc., 76 F.3d 1245, 1252 (1st. Cir. 1996) (same where fraud plaintiff had received "storm warnings" that statements may have been false); *Young v. LePone*, 305 F.3d 1, 8 (1st Cir. 2002) (same). Yet States have known for decades that the published AWPs for many prescription drugs bear "little relationship to the drugs' pricing in the marketplace." Mont. Cplt. ¶ 173; Nev. Cplt. ¶ 136.[7]

First, as early as 1974, the predecessor agency to HHS publicly announced that when States peg Medicaid reimbursement to AWPs, they frequently pay "in excess of actual acquisition cost to the retail pharmacist." 39 Fed. Reg. 41,480 (Nov. 27, 1974). In 1975, the same agency specifically warned States that "AWP data are frequently inflated," and therefore urged States to stop reimbursing Medicaid providers on the basis of AWP.[8] Second, in 1984, the States were advised that actual prices charged to retail pharmacies could be as much as 42% below AWP and a federal audit of drug prices in six States concluded that AWP was not "even an adequate estimate of the prices providers are generally paying for their drugs." *Medicare Action Transmittal No. 84-72, reprinted in Medicare & Medicaid Guide* (CCH) ¶ 34,157 at 10,197 (1984) (Ex. 4). This Transmittal recommended that States "abandon the AWP reimbursement methodology." *Id.*[9] Third, in the early 1990s, HCFA publicly disapproved the Medicaid drug reimbursement plans of at least three States that proposed to use undiscounted

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[7] For purposes of this argument, defendants rely on the cited public record documents, which may be considered in this motion. Under Rule 12(b)(6), the Court may consider "matters of public record," such as the "published reports of administrative bodies." *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196-97 (3d Cir. 1993), *aff'd*, 215 F.3d 407 (3d Cir. 2000). *See also Alternative Energy, Inc. v. Saint Paul Fire & Marine Ins. Co.*, 267 F.3d 30, 33 (1st Cir. 2001). The Court may also consider "documents central to the plaintiff's claim" and "documents sufficiently referred to in the complaint." *Watterson v. Page*, 987 F.2d 1, 3 (1st Cir. 1993). *See also Chief Justice Cushing Highway Corp. v. Limbacher*, 145 F. Supp.2d 108, 110 (D. Mass. 2001) (same).

[8] *See* 40 Fed. Reg. 34,576-78 (Aug. 15, 1975); *see also* 40 Fed. Reg. 32,284-293 (July 31, 1975).

[9] *See also* HHS IG Report, *Use of Average Wholesale Prices in Reimbursing Pharmacies in Medicaid and the Medicare Prescription Drug Program* (Oct. 1989), *reprinted in Medicare & Medicaid Guide* (CCH) ¶ 38,215 (1990) (Ex. 5) (warning States that "AWP cannot be the best -- or even an adequate -- estimate of the price providers generally pay for drugs. AWP represents a list price and does not reflect several types of discounts.").

AWPs because it was so well-known that the published AWPs often exceeded provider acquisition costs.[10] Fourth, as the Court will recall, reports prepared by the federal government demonstrate that Congress, HHS, and the States have long known that published AWPs frequently are much higher than the prices at which providers actually purchase drugs.[11]

Finally, in 1996, HHS conducted an audit of pharmacy acquisition costs for drugs reimbursed under ***Montana's*** state Medicaid program.[12] HHS determined that AWP exceeded provider purchase prices in Montana by as much as 31.6% for brand-name drugs and 67.4% for generic drugs. Ex. 8 at appendix 2. On the basis of this audit, HHS concluded that Montana faced a "significant difference between AWP and pharmacy acquisition costs," and should consider the results of the audit in "determining any future changes to pharmacy reimbursement for Medicaid drugs." *Id.* at 6. In response to the audit, the Montana Department of Public Health and Human Services still chose to keep its AWP-based system of reimbursement. *Id.* appendix. 4. On the basis of this 1996 audit (and similar ones conducted by HHS in several other States), in 1997 HHS revised the model *State Medicaid Manual* to include an advisory to

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[10] *See Louisiana v. United States Dep't of Health & Human Servs.*, 905 F.2d 877, 879 (5th Cir. 1990) (observing that "[t]here has been considerable doubt for a number of years whether AWP provides the closest estimate of the price generally and currently paid by pharmacists for drugs."); *In re Arkansas Dep't of Human Servs.*, 1991 WL 634857 (HHS Dep't App. Bd. Aug. 22, 1991) (disallowing reimbursement claim and noting that the State "was aware that pharmacists generally paid less than" AWP) (Ex. 6); *In re Oklahoma Dep't of Human Servs.*, 1991 WL 634860 (HHS Dep't App. Bd. Aug. 13, 1991) (same result; noting "problem" caused by States' use of AWP as a "measure of acquisition cost") (Ex 7). *See also Rite Aid of Pennsylvania, Inc. v. Houstoun*, 171 F.3d 842, 847 (3d Cir. 1999) (noting that "HCFA informed [Pennsylvania] that it would not accept AWP levels for 'EAC without a significant discount being applied,' unless the [State] provided documentation that the actual acquisition cost equaled the full AWP.").

[11] *See, e.g.*, Majority Staff Report, Special Comm. of Aging, U.S. Senate, *Prescription Drug Prices: Are We Getting Our Money's Worth?*, S. Rep. 101-49, at 11 (1989) (noting that "hospitals, HMOs, and nursing homes that contract with wholesalers achieve discounts up to 99% off AWP"); 39 Fed. Reg. 41,480 (Nov. 27, 1974) (observing that when States peg Medicaid reimbursement to AWP they often pay "in excess of actual acquisition cost to the retail pharmacist").

[12] *See* HHS, *Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Montana Department of Health and Human Services* (July 11, 1996) (Ex. 8).

state Medicaid administrators that AWPs often exceed actual acquisitions costs for prescription drugs.[13]

Under these particular, extraordinary circumstances, neither Montana nor Nevada can claim it was misled, deceived, or defrauded by the allegedly inflated AWPs about which the States now complain. Not only did these States know that many AWPs represented a list "sticker" price well above provider acquisition cost, these States decided to maintain an AWP-based system of reimbursement in the face of repeated studies by HHS. Unlike the Medicare program, which was required by Congress to maintain AWP as the reimbursement benchmark in order to adequately compensate physicians, the States were under no such requirement. Indeed, several States have heeded the HHS advice and adopted different reimbursement benchmarks for prescription drugs. But Nevada and Montana decided for their own policy reasons to stick with AWP. That may have been an appropriate Medicaid policy choice for each State, but Nevada and Montana cannot now claim that they were defrauded and misled. *See* Mont. Cplt. ¶¶ 654-73; Nev. Cplt. ¶¶ 423-43.

B. Nevada Lacks Standing to Assert its Racketeering Claim and Alleges No Cognizable Enterprise.

Nevada's AWP claims under the Nevada civil RICO statute, Nev. Rev. Stat. § 207.400(1)(c), fail for two fundamental reasons. First, the State lacks standing to sue for monetary damages under its civil RICO statute. The statute provides a private right of action to any "person" who is "injured in his business or property by reason of any violation of [§ 207.400]." Nev. Rev. Stat. § 207.470. The term "person" is not defined in the statute, but is defined in the Preliminary Chapter of the General Provisions of the Nevada Statutes to ***exclude***

[13] *See* HHS IG, *Medicaid Pharmacy -- Actual Acquisition Cost of Generic Prescription Drug Products* at 1, A-06-97-00011, *reprinted in Medicare & Medicaid Guide* (CCH) ¶ 45,559 (Aug. 4, 1997) (Ex. 9 hereto).

any government, governmental agency, or political subdivision of a government, unless expressly included by a specific statute. *See* Nev. Rev. Stat. § 0.039. Further, federal courts have construed the federal RICO statute to bar civil suits for damages by the federal government. *See, e.g., United States v. Bonanno Organized Crime Family*, 879 F.2d 20, 21-27 (2d Cir. 1989) (federal government not a "person" with standing to sue for damages under civil RICO statute). Because the Nevada RICO statute is "patterned" after the federal RICO statute, *Allum v. Valley Bank of Nevada*, 849 P.2d 297, 301 (Nev. 1993), the Court should apply this construction here. Accordingly, the Nevada RICO statute bars civil suits for damages by the state government.

Second, even if the State has standing to assert a civil RICO claim for damages, Nevada does not set forth a single viable RICO enterprise. Nevada purports to assert a series of 39 "association-in-fact" enterprises involving each of the 13 defendant Companies and each one of three identified publishers of AWPs. *See* Nev. Cplt. ¶¶ 449-53. These "Manufacturer-Publisher Enterprises" are identical to the "Manufacturer-Publisher Enterprises" alleged by the private plaintiffs in the AMCC. *See* AMCC ¶ 624. Accordingly, Nevada's alleged enterprise fails for the same reasons previously set forth in the motion to dismiss the AMCC.[14]

III. THE COMPLAINTS LACK THE PARTICULARITY REQUIRED BY RULE 9(B).

Under Federal Rule of Civil Procedure 9(b), all claims in which fraud "lies at the core of the action" must be pleaded with particularity, with plaintiffs specifying the time, place, and content of each assertedly fraudulent statement, and the allegedly fraudulent acts of each Company. *Hayduk v. Lanna*, 775 F.2d 441, 443-44 (1st Cir. 1985); *Suna v. Bailey Corp.*, 107

[14] Consol. Mem. in Support of Deft's Mot. to Dis. the AMCC at 7-8 (Aug. 1, 2003) ("Consol. Mem.") at 14-17.

F.3d 64, 73 (1st Cir. 1997). Because fraud "lies at the core of the action" in all of plaintiffs' claims, the Best Price claims and major portions of the AWP claims fail under Rule 9(b).[15]

A. The Best Price Claims Are Too Cursory to Survive Dismissal.

Even if not preempted, and even if they satisfy the elements of the Montana and Nevada statutes upon which they are based, the Best Price claims fail under Rule 9(b). Although the Montana and Nevada Complaints each are well over 100 pages long, the Best Price claims are alleged in only a handful of general paragraphs. For example, the States allege that "each defendant did not report the actual best price or AMP, but instead (i) reported higher prices and (ii) excluded discounts and other inducements offered to physicians." Nev. Cplt. ¶ 392; Mont. Cplt. ¶ 622. The States also allege "on information and belief" that various unnamed "drug manufacturers" also "hid rebates" by not including "credit memos" and "other rebates" in the relevant best price calculations. Nev. Cplt. ¶¶ 393-96. Nevada provides only two purported examples, referring to the recent settlements involving AstraZeneca's product Zoladex and the Pfizer/legacy Warner-Lambert product Lipitor. Nev. Cplt. ¶¶ 398-403; *see also* Mont. Cplt. ¶¶ 623-26 (also referring to the GSK settlement involving Flonase and Paxil sold to a single purchaser and the Bayer settlement involving Cipro sales to a single HMO). Taken together, these allegations are woefully deficient under Rule 9(b).

First, Montana and Nevada do not specify a single allegedly fraudulent best price report, nor do they identify the dates or "fraudulent" content of any such reports. Second, there is no discount identified that should have been included in the best price calculation, nor any "free good" "rebate," "educational grant," or "credit memo" that should have been included. Nor do the

[15] *See Ahmed v. Rosenblatt*, 118 F.3d 886, 889 (1st Cir. 1997) (Rule 9(b) applies to RICO claims); *United States v. Melrose-Wakefield Hosp.*, 2003 WL 21228801, *3 (D. Mass. May 21, 2003) (same for False Claims Act claims); *Stires v. Carnival Corp.*, 243 F. Supp.2d 1313, 1322 (M.D. Fla. 2002) (same for deceptive trade practice claims in "most courts").

States identify any company or drug for which a best price allegedly was erroneously reported, other than a few references to recent settlements. The Best Price claims accordingly fail to satisfy Rule 9(b) for the vast majority of defendants and drugs identified by plaintiffs.

A federal magistrate recently recommended dismissal under Rule 9(b) of similarly deficient Best Price claims against Merck & Co., Inc. In *LaCorte v. Merck & Co., Inc.*, No. 99-3807, slip op. at 6 (E.D. La. Aug. 27, 2003) (Ex. 10), the plaintiff alleged that Merck failed to report an accurate best price for its drug Pepcid over a defined time period. However, the Magistrate recommended dismissal of the best price claims (predicated on the federal False Claims Act) with prejudice because the complaint (1) provided "no particular dates of [best price] report submissions," (2) did not explain "why the [best price] information was false," (3) did not state "who submitted the report," and (4) also failed to "refer to a single instance where [defendant] submitted prices to the government that [were] distinct from those paid by [providers]." *Id.* at 6, 16. As in *LaCorte*, Montana and Nevada's failure to identify a single particular best price report compels dismissal of the best price claims.

B. The Allegations Relating To PBMs And "Other" Alleged "Hidden and Improper Inducements" Are Also Devoid of Particulars.

In a mere nine paragraphs of each Complaint, the States purport to encompass within this lawsuit hundreds or thousands of drugs outside the Medicare and Medicaid frameworks through private payor contracts with pharmacy benefit managers, or "PBMs." *See* Mont. Cplt. ¶¶ 201-209; Nev. Cplt. ¶¶ 164-172. This PBM theory applies specifically to the "deceptive trade practice" claims on behalf of state residents. The theory is identical to the one asserted by the

class action plaintiffs in the AMCC, and should be dismissed under Rule 9(b) for the same reasons previously explained by the AMCC defendants. *See* Consol. Mem. at 7-8.[16]

Similarly, in four short paragraphs, the States seek to include other alleged practices as part of their AWP claims, such as the "improper use of free samples" and "other non-public financial inducements" such as "volume discounts, rebates, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness, and educational and promotional grants." Mont. Cplt. ¶¶ 181-84; Nev. Cplt. ¶¶ 144-47. These sweeping, all-inclusive allegations, devoid of particulars as to the conduct of individual defendants, are plainly insufficient under Rule 9(b) for the same reasons explained in the motion to dismiss the AMCC. *See* Consol. Mem. at 7-8.[17]

CONCLUSION

For the foregoing reasons, the Second Amended Complaint filed by the State of Montana and the Amended Complaint filed by the State of Nevada should be dismissed.

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[16] Relatedly, all claims involving drugs not specifically named in Montana and Nevada's Complaints should be dismissed in accordance with this Court's prior ruling in the AWP MDL. *See In re Pharm. Indus. AWP Litig.*, 263 F. Supp.2d 172, 194 (D. Mass. 2003) ("to the extent the complaint seeks to encompass all 'brand name drugs' . . . named drugs without a specific fraudulent AWP, or generic multi-source drugs, the motion to dismiss is ***ALLOWED***.") (emphasis in original).

[17] The States' AWP claims based on multiple-source drugs (Mont. Cplt. ¶¶ 185-200; Nev. Cplt. ¶¶ 148-63) should be dismissed for the same reasons that these claims were dismissed from the AWP MDL. *See In re AWP Litig.*, 263 F. Supp.2d at 194 n.11. The States also assert claims for punitive damages as Counts of their Complaints. *See* Mont. Cplt. ¶¶ 692-93 (Count V); Nev. Cplt. ¶¶ 478-79 (Count VI). These claims, however, are merely demands for a particular type of relief, and should be dismissed along with the substantive causes of action. *See, e.g., Byrne v. Nezhat*, 261 F.3d 1075, 1093 n.34 (11th Cir. 2001) ("a prayer for punitive damages is not an independent cause of action"); *Indemnified Capital Investments, S.A. v. R.J. O'Brien Assocs., Inc.*, 12 F.3d 1406, 1413 (7th Cir. 1993) (plaintiff "must prevail on one of its substantive claims in order to receive an award of punitive damages.").

Respectfully submitted,

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HOECHST MARION ROUSSEL, INC.

IMMUNEX CORP.

JANSSEN PHARMACEUTICAL PRODUCTS, L.P.

JOHNSON & JOHNSON

MCNEIL-PPC, INC.

NOVARTIS PHARMACEUTICALS CORPORATION

ONCOLOGY THERAPEUTICS NETWORK CORPORATION

ORTHO BIOTECH

PFIZER, INC.

PHARMACIA CORPORATION

PHARMACIA & UPJOHN, INC.

SCHERING-PLOUGH CORPORATION

SMITHKLINE BEECHAM CORPORATION

TAP PHARMACEUTICAL PRODUCTS, INC.

WARRICK PHARMACEUTICALS CORPORATION

CERTIFICATE OF SERVICE

I hereby certify that on this 15th day of September, 2003, a true and correct copy of the foregoing Motion to Dismiss the State of Montana's Second Amended Complaint and the State of Nevada's Amended Complaint, and the Consolidated Memorandum in support thereof, was served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL No. 1456.

Jason A. Levine

ROPES & GRAY LLP
ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624 T 617-951-7000 F 617-951-7050
BOSTON NEW YORK SAN FRANCISCO WASHINGTON, DC

September 15, 2003

John R. Therien
(617) 951-7966
jtherien@ropesgray.com

Clerk for Civil Business
United States District Court
for the District of Massachusetts
U.S. Courthouse
One Courthouse Way, Suite 2300
Boston, MA 02210

Re: In re: Pharmaceutical Industry Average Wholesale Price Litigation MDL No. 1456

Dear Sir/Madam:

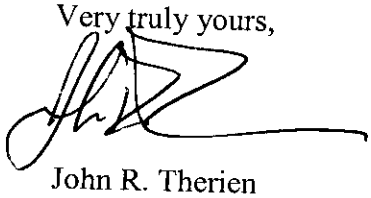
Enclosed for filing please find the following:

(1) Defendants' Motion to Dismiss the State of Montana's Second Amended Complaint and the State of Nevada's Amended Complaint; and

(2) Appendix of Exhibits.

Please date-stamp the enclosed copy of this cover letter and return it to our messenger. Thank you.

Very truly yours,



John R. Therien

cc: All counsel of record (via Verilaw)

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